UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION,

PESTICIDES AND

TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of Resubmission of Non-GLP Study under FIFRA 6(a)(2): Amended Glove Permeation Testing Study Submitted Under FIFRA 6(a)(2) by The Dow Chemical Company in Support of **UCARCIDE™ P 200 Antimicrobial**.

TO: Dennis Edwards, Chief
Marshall Swindell, Product Manager, Team 33
Regulatory Management Branch I
Antimicrobials Division (7510C)

FROM: Doreen Aviado, Biologist
Team Two
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

THRU: Nader Elkassabany, Team Leader
Team Two
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

Norm Cook, Chief
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

Registrant: The Dow Chemical Company

DP Barcode: D289484 (S633154)

Pesticide Chemical No./Name: 129017 - 1,2-Benzenedicarboxaldehyde (ortho-phthalaldehyde, OPA)

EPA Reg. No.: 464-713

MRID No.: 457835-01

Action Requested:

The Antimicrobials Division (AD), Product Management Team 33, requested the Risk Assessment Science Support Branch (RASSB) conduct a review of a non-GLP study submitted October 21, 2002 under FIFRA 6(a)(2) by The Dow Chemical Company in support of **UCARCIDE™ P 200 Antimicrobial** (EPA Reg. No. 464-713).

Background:

The submitted glove permeation testing study conducted with ortho-phthalaldehyde (OPA) permeation in a 5.5% OPA solution (MRID 457835-01) is actually an amended resubmission of a study previously reviewed by the Agency (D. Aviado, D287982, March 6, 2003) entitled "Vol. 1: Miller Nelson Research Inc. (2002). *Glove Permeation Testing with 5.5% Aqueous o-Phthalaldehyde Solution*, ASTM Guideline 739-99A; The Dow Chemical Company and Advanced Sterilization Products, 9 pages" (MRID 457793-01). The "*Amended Report*" (MRID 457835-01) revises text on page 5 to clarify the procedures followed under "Materials and Methods". The minor revisions do not entail changes in study design/protocol, nor impact test results obtained. No other changes have been made to the original study (MRID 457793-01) to warrant a re-review. Therefore, the review memorandum created for D287982 remains pertinent to this resubmission and is attached for reference.

Attachment

cc: Doreen Aviado/RASSB/AD (7510C)
Chemical File
Circulation

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Cursory Review of Non-GLP Study:
Review of Glove Permeation Testing Study
Submitted Under FIFRA 6(a)(2) by The Dow Chemical Company
in Support of **UCARCIDE™ P 200 Antimicrobial**.

TO: Dennis Edwards, Chief
Marshall Swindell, Product Manager, Team 33
Regulatory Management Branch I
Antimicrobials Division (7510C)

FROM: Doreen Aviado, Biologist
Team Two
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

THRU: Nader Elkassabany, Team Leader
Team Two
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

Norm Cook, Chief
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

Registrant: The Dow Chemical Company

DP Barcode: D287982 (S628373)

Pesticide

Chemical No./Name: 129017 - 1,2-Benzenedicarboxaldehyde (ortho-phthalaldehyde, OPA)

EPA Reg. No.: 464-713

MRID No.: 457793-01

Action Requested:

The Antimicrobials Division (AD), Product Management Team 33, requested the Risk Assessment Science Support Branch (RASSB) conduct a review of a non-GLP study submitted October 16, 2002 under FIFRA 6(a)(2) by The Dow Chemical Company in support of **UCARCIDE™ P 200 Antimicrobial** (EPA Reg. No. 464-713). The submitted data is a glove permeation testing study conducted to determine the resistance of several different glove media against ortho-phthalaldehyde (OPA) permeation in a 5.5% OPA solution.

Background:

UCARCIDE™ P 200 Antimicrobial (99.8% OPA a.i.) is a crystalline solid which has been registered since July 3, 1997 as a technical source, manufacturing-use product (MUP), for formulators of industrial bactericides and preservatives. The product was initially developed by, and registered to, Union Carbide Corporation (EPA Reg. No. 10352-51) before being transferred to Dow Chemical on September 19, 2001.

Current registered product labeling (October 12, 2001) and Material Safety Data Sheet (MSDS) information (March 13, 2001) on file for **UCARCIDE™ P 200 Antimicrobial** cites personal protective clothing requirements and precautionary information for industrial workers using the MUP concentrate.

Handlers of **UCARCIDE™ P 200 Antimicrobial** (99.8% OPA a.i.)

Information Source	Precautionary Statements	Personal Protective Equipment (PPE)
Product Labeling	Danger. Corrosive. Irreversible eye damage/skin burns. Harmful if inhaled. May be fatal if swallowed. Harmful if absorbed through skin. Prolonged/repeated skin contact may cause allergic reactions. Asthmatic signs/symptoms in hyper-reactive persons. Do not get in eyes, on skin, on clothing. Avoid breathing vapor. Do not swallow. Wash thoroughly with soap and water after handling.	"Wear goggles, protective clothing, and butyl gloves" "Remove contaminated clothing and wash before reuse" *(Note: No needed respiratory protection cited.)*
MSDS	Danger. Corrosive. Irreversible eye damage/skin burns. Harmful if inhaled. May be fatal if swallowed. Harmful if absorbed through skin. Prolonged/repeated skin contact may cause allergic reactions. Aspiration may cause lung damage. Do not get in eyes, on skin, on clothing. Avoid	"NIOSH/MSHA approved respirator, safety glasses/monogoggles, and butyl rubber gloves" Ensure "satisfactory room ventilation" and presence of

	breathing dust. Do not swallow. Wash thoroughly after handling. Use with adequate ventilation.	"eye bath/safety shower"

The study entitled "Vol. 1: Miller Nelson Research Inc. (2002). *Glove Permeation Testing with 5.5% Aqueous o-Phthalaldehyde Solution*, ASTM Guideline 739-99A; The Dow Chemical Company and Advanced Sterilization Products, 9 pages" (MRID 457793-01) was submitted for Agency review as follow-up to two OPA glove permeation studies conducted in 1997 and 1998 by the former product registrant of record, Union Carbide Corporation. The 1997/1998 studies looked at glove breakthrough times using a dilute 0.55% aqueous OPA solution. The present 2002 study determines the breakthrough times for similar glove types (as were used in the previous studies) using a more concentrated 5.5% aqueous OPA solution. The study results are intended to be used by the product manufacturer in determining the appropriate glove media to be worn during 8 hr. workplace contact with formulated 5.5% OPA solutions.

Although the Agency has no formal FIFRA guideline requirements set for the conduct of glove permeation/clothing penetration studies, EPA acknowledges test standards set by the American Society for Testing and Materials (ASTM) as appropriate for generating such data. Specifically, registrants are referred to ASTM Test Method F-739-99A, "*Standard Test Method for Resistance of Protective Clothing Materials to Permeation by Liquids or Gases Under Conditions of Continuous Contact*" for developing a permeation test cell and analytical parameters. Since the submitted study followed ASTM Guideline 739-99A methodology (without modifications/deviations to the standard protocol) it was therefore not critiqued by the Agency for compliance.

Summary of Findings/Recommendations:

The study tested nine glove media samples in triplicate (representing seven different glove model types) against the 5.5% OPA solution to determine which gloves were most resistant to permeation. Each test series was run for 8 hours or until breakthrough was detected. Initial samples were collected after 15 minutes of contact and subsequently at 30-minute intervals. A summary table of results is shown below.

Time Required for Breakthrough to Occur in Various Glove Media Exposed to 5.5% OPA Solution.

Rank	Glove Media	Model	Avg. Thickness (mil)	Average Breakthrough Time across Trials 1-3 (Minutes)
1	Butyl Rubber	North, X5113	18.2	> 480 (i.e., 8 hrs.)
2	PVC	Best, Black Knight CE 0334	46.2	189
3	Latex	Micro-Touch D09211 (Double Layer)	17.7	32
4	Nitrile	Best, N-DEX 7005	4.7	30
5	Latex	Micro-Touch 0204 14132 (Double Layer)	15.5	14
6	Latex	Micro-Touch D09211 (Single Layer)	8.8	11

7	Synthetic Latex	Allergard II 105027	9.0	5
8	Latex	Micro-Touch 0204 14132 (Single Layer)	7.4	2
9	Polyethylene	Ansell-Edmont 35-124	1.1	2

- A cursory review of the submitted glove permeation testing study reveals no overt deficiencies. Although the Agency has no set guidelines for determining the acceptability of such study protocols/data, there is a high degree of confidence in the generated data results since the study protocol did not deviate from the ASTM F-739-99A standard methodology recommended by AD/RASSB.

- The study results indicate that butyl rubber gloves were impervious to the 5.5% OPA aqueous solution for the 8 hour test duration and are therefore ranked as the best choice in glove protection in comparison with the breakthrough times of the other test samples. The least protective glove medium was polyethylene with a breakthrough measured at 2 minutes across all three test trials. The results of this 2002 study were consistent with the finding of the previous 1997/1998 trials.

- The choice of butyl rubber gloves as cited on the **UCARCIDE™ P 200 Antimicrobial** (99.8% OPA a.i.) product labeling/MSDS is protective of pesticide formulators in contact with manufactured diluted 0.55% to 5.5% OPA aqueous solutions. However, it is unknown if either Union Carbide Corporation or Dow Chemical generated any glove permeation data to support the use of butyl rubber gloves as suitable PPE during handler and postapplication contact with the 99.8% technical chemical as a crystalline solid concentrate. Due to the nature of these glove permeation studies being submitted as FIFRA 6(a)(2), the PM may wish to have the registrant confirm if certain data exist which were used as the basis for the glove PPE selection of butyl rubber for **UCARCIDE™ P 200 Antimicrobial** (99.8% OPA a.i.). It may be possible that all mixing/loading/application steps are done using automated/closed systems as engineering controls to prevent direct worker contact with the 99.8% a.i. product concentrate. The product labeling does not indicate application directions.

- Due to the acute toxicity profile of OPA, and a desire for labeling and MSDS consistency, the Product Manager is encouraged to require amended product labeling which includes the MSDS respiratory PPE statement “NIOSH/MSHA approved respirator”.

cc: Doreen Aviado/RASSB/AD (7510C)
Chemical File
Circulation

Sign-off Date : 05/0503

DP Barcode No. : D289484